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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,371	12/10/2001	Ian R. Reid	HO-P02194US0	6234

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EXAMINER	
JIANG, SHAOJIA A	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/016,371	REID, IAN R.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,8,9,11-15 and 17-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6, 8-9, 11-15, and 17-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicant's amendment and response filed on February 22, 2005 wherein claim 7 is cancelled and claims 1-4, 6, 8-9, 11-15, and 17-22 have been amended. Claims 5, 10, 16-21 are cancelled previously.

Currently, claims 1-4, 6, 8-9, 11-15, and 17-22 are pending in this application.

Claims 1-4, 6, 8-9, 11-15, and 17-22 as amended now are examined on the merits herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6, 8-9, 11-15, and 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pak et al. (US 4,851,221 of record) in view of *"Calcium and Serum Cholesterol"* (Nutrition Review Vol. 25, No. 10, pp. 298 - 300, 1967; PTO-1449 submitted March 12, 2002) or Mitchell et al (*"The Effect of Oral Calcium on Cholesterol Metabolism"* PTO-1449 submitted March 12, 2002).

Pak et al. discloses that administering a calcium supplemental composition comprising calcium citrate at a dose 1g (60 meq/day) or 1.5-2.75 g calcium/day to a postmenopausal woman is useful in treating various conditions associated to a postmenopausal woman such as hypoparathyroidism, osteoporosis, bone loss,

hyperphosphatemia and hypertension (see col.1 lines 49-50, 63-68; col.3 lines 42-43, 46; col.8 line 35-36; col.9 line 50-67; claim 20). Pak et al. disclose a daily administration. The calcium citrate composition of Pak et al. is prepared from pre-mix preparation with a calcium/citrate molar ratio of 1.25 of citric acid and a calcium compound such as calcium hydroxide (see abstract, and claim 18-20).

Note that Pak et al. discloses the same effective amounts or doses of calcium citrate to be administered to the postmenopausal woman as instantly claimed.

Pak et al. does not expressly disclose the employment of the calcium composition in methods of increasing a high-density lipoprotein level (HDL) in plasma or a ratio of HDL to LDL in a postmenopausal woman. Pak et al. does not expressly disclose measuring the high-density lipoprotein level in said woman. Pak et al. does not expressly if the high-density lipoprotein level in plasma is increased, the administering the calcium composition for at least about two months.

The reference *"Calcium and Serum* Cholesterol" teaches that oral calcium supplements are known to have hypocholesteremic effect in a person or subject with raised serum cholesterol (see abstract); cholesterol levels are known to be measured before and at the end of calcium administration in the persons. See the first paragraph of page 299.

The reference *"The Effect of Oral Calcium on Cholesterol Metabolism"* teaches that that serum cholesterol levels are known to be measured using an Auto Analyser (a known method) to test the effect of oral calcium on cholesterol metabolism. See page 916.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to administer the calcium composition to a postmenopausal woman daily or at least two or six months for increasing a high-density lipoprotein level (HDL) in plasma or a ratio of HDL to LDL in said postmenopausal woman; and to measure the high-density lipoprotein level in postmenopausal woman who administering calcium citrate for increasing HDL level.

One having ordinary skill in the art at the time the invention was made would have been motivated to administer the calcium composition to a postmenopausal woman daily or at least two months for increasing a high-density lipoprotein level (HDL) in plasma or a ratio of HDL to LDL in said postmenopausal woman, since administering a calcium supplemental composition comprising calcium citrate at a dose 1g (60 meq/day) or 1.5-2.75 g calcium/day to a postmenopausal woman is known to be useful in treating various conditions associated to a postmenopausal woman such as hypoparathyroidism, osteoporosis, bone loss, hyperphosphatemia and hypertension. Moreover, it is well-known that the various conditions associated to a postmenopausal woman also include hypercholesterol levels due to menopause in need of increasing a high-density lipoprotein level (HDL) in plasma or lowering low-density lipoprotein level (LDL), or increasing a ratio of HDL to LDL in said postmenopausal woman.

Thus, the patient population in Pak et al. is deemed to encompass or overlap or coincide the patient herein for increasing HDL level in plasma.

Therefore, one of ordinary skill in the art would have reasonably expected that calcium citrate would have beneficial therapeutic effects and usefulness in methods of

increasing HDL level in plasma in postmenopausal women, by administering the same effective amounts of calcium citrate of Pak et al. to the same or overlapping patient population.

Furthermore, measuring cholesterols or lipoproteins levels of patients or humans before, during, and after therapeutic treatments, including with calcium, and determining the administration for at least for two or six months, are well known in the art according the two cited references above, and are considered well within conventional skills in medical practice and pharmaceutical science, involving merely routine skill in the art.

Response to Argument

Applicant's arguments filed February 22, 2005 with respect to the rejection made under 35 U.S.C. 103(a) of record in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art as further discussed below.

First, Applicant asserts that the secondary references teach away from the claimed invention. Contrary to Applicant's assertion, the reference *"Calcium and Serum* Cholesterol" teaches that oral calcium supplements are known to have hypocholesteremic effect in a person or subject with raised serum cholesterol (see abstract); the reference further teaches that "[w]eekly estimations of serum total cholesterol, total lipids, and beta-lipoproteins were made.", and "[t]he maximum fall in serum cholesterol was observed after one week of calcium supplements" (see page 299, the last para of the right column).

Moreover, Mitchell et al in *"The Effect of Oral Calcium on Cholesterol Metabolism"* teaches that "[t]hese results show that calcium salts have an appreciable effect on the excretion of cholesterol and its metabolites. Calcium in the forms administered caused faecal cholesterol excretion to increase." (see page 920, "Discussion", 5th para.).

As noted in MPEP 2123:

> "A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Merck & Co. v.Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied,493 U.S. 975 (1989). See also Celeritas Technologies Ltd. v. Rockwell International Corp., 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir.1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal isshown to be less than optimal does not vitiate the fact that it is disclosed.").

Therefore, the secondary references as a whole is seen to render the claimed invention obvious, not teaching away as Appellant asserts.

In view of the rejections to the pending claims set forth above, no claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Anna Jiang, Ph.D.
Primary Examiner
Art Unit 1617
May 10, 2005